

Applicants: Breslow et al.
Serial No.: 10/054,585
Filed : November 12, 2001
Page 2

Rejection under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 14 and 19-32 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to point out and distinctly claim the subject matter which applicants regard as their invention. Specifically, the Examiner alleges that counter ions for certain embodiments of R_1 , namely $-\text{CO}_2^-$, $-\text{N}^+(\text{CH}_3)_3$, and $-\text{SO}_3^-$, must be specified.

In response, applicants respectfully traverse the Examiner's rejection.

35 U.S.C. §112, second paragraph, states that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which applicant regards as his invention; and the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant." According to M.P.E.P. §2171, these two requirements under 35 U.S.C. §112, second paragraph, are separate.

The claimed invention provides phthalocyanine compounds whose chemical structures are set forth in the claimed compositions and uses thereof. These chemical structures of the claimed phthalocyanine compounds are well defined in claim 14. One skilled in the art would not require any further information in order to fully understand the molecular structures (i.e. metes and bounds) of these phthalocyanines, including the structures of the recited R_1 embodiments at issue, as it is well known in the art that charged compounds exist in chemical

Applicants: Breslow et al.
Serial No.: 10/054,585
Filed : November 12, 2001
Page 3

media with oppositely charged entities, such as counter ions.

In support of rejecting the claims and applicants' arguments, the Examiner sets forth four reasons.

First, the Examiner cites *Ex Parte Diamond*, 123 USPQ 167 (1959), as allegedly standing for the proposition that counter ions must be specified. In response, applicants disagree with the Examiner's interpretation of the *Diamond* decision. *Ex Parte Diamond* is an appeal from a final rejection of claims providing compositions comprising the active portion of an insecticide without disclosing other moieties of the compound. The court states that "[c]laim 1 merely gives the formula of this radical, the remainder of the compound being undefined. The claim, therefore, is in the category of those employing 'dangling valences' to indicate undefined substituents", *Ex Parte Diamond*, 123 USPQ at 167 (1959). In other words, a "dangling valence claim" is one that provides a partial chemical structure (i.e. a radical) with open covalent bonding areas to which undisclosed moieties may attach forming many different types of compounds. In contrast, claim 14 of the subject application provides a complete chemical structure of the claimed phthalocyanines. All moieties are disclosed with no open covalent bonding areas. Hence, the entire phthalocyanine structure is defined. Applicants therefore contend that the holding of *Ex Parte Diamond* is inapposite to instant claim 14 and dependent claims 19-32, as claim 14 is clearly not a dangling valence claim as defined in *Ex Parte Diamond*.

Second, the Examiner asks: "how is the public to understand

Applicants: Breslow et al.
Serial No.: 10/054,585
Filed : November 12, 2001
Page 4

the metes and bounds of the claimed subject matter" without the specific disclosure of counter ions. In response, applicants again stress MPEP §2173.02, which states that the inquiry for definitiveness under 35 U.S.C. §112, second paragraph, is "whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definitiveness of claim language must be analyzed, not in a vacuum, but in light of: (A) the content of the particular application disclosure; (B) the teachings of the prior art; and (C) the claim interpretation that would be given by *one possessing the ordinary level of skill in the pertinent art* at the time the invention was made" (emphasis added). The state of the pertinent art at the time the application was filed is the standard for determining whether the claims are definite. Applicants maintain that based on the level of the art at the time of filing, one of ordinary skill, by reading the chemical structure of the instant compound set forth in claim 14, would clearly understand the metes and bounds of this invention. The metes and bounds of the instant compounds are defined *in the structures themselves* as set forth in the claims. It is irrelevant to the issue of clarity whether one of ordinary skill understands the exact chemical milieu in which a particular charged molecule exists. That is, counter ions which would in fact accompany the claimed compounds *are not themselves part of this invention*.

Third, the Examiner states that there is "an infinite number" of possible counter ions and asks whether all are claimed. The Examiner alleges that without the disclosure of the counter ions, the scope of the claim is too broad. In response, applicants disagree with the Examiner's position and

Rr

Applicants: Breslow et al.
Serial No.: 10/054,585
Filed : November 12, 2001
Page 5

again note that the counter ions themselves are not part of the invention, as they are mere balancing charges to the claimed compounds. Again, applicant maintains that the metes and bounds of the claimed compounds are well defined in claim 14 of the subject application, and do not include the counter ions which merely define the chemical milieu in which the claimed compounds may exist. Further, applicants stress that the "[b]readth of a claim is not equated with indefiniteness", *In re Miller*, 441 F.2d. 689, at 689, 169 USPQ 597 (CCPA 1991). According to M.P.E.P. §2173.04, "[i]f the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph."

Fourth, the Examiner, citing *In re Zeltz*, 13 USPQ2d 1320, states that "[a]n essential purpose of patent examination is to fashion claims that are precise, clear, correct and unambiguous" and alleges that the lack of specified counter ions renders claim 14 ambiguous. In response, applicant again disagrees with the Examiner's position. Claim 14 is not ambiguous because the structures of the phthalocyanines are well-defined and clearly set out in the claims. No interpretation as to the chemical structure of the phthalocyanines can be inferred other than the structure provided in claim 14. Only the medium in which the claimed compound exists may vary, and again, this medium is not part of the invention.

Applicants maintain that none of the four reasons in support of the rejection offered by the Examiner has any basis in fact

Applicants: Breslow et al.
Serial No.: 10/054,585
Filed : November 12, 2001
Page 6

or in law. The Examiner has not put forth any factual reference indicating that a skilled chemist at the time the application was filed would be unable to understand the invention, i.e., the instant phthalocyanines, as provided in the claims of the subject application. The Examiner also has not provided any legal basis for requiring applicants to amend the claims to recite counter ions. Accordingly, applicants maintain that the metes and bounds of the claimed phthalocyanine compounds and related methods and compositions are clear from the claims.

In view of the remarks above, applicants maintain that claims 14-32 satisfy the requirements of 35 U.S.C. §112, second paragraph.

Rejections under 35 U.S.C. §112, First Paragraph

The Examiner rejected claim 28-32 under 35 U.S.C. §112, first paragraph, as allegedly not enabled by the specification. The Examiner states that the specification does not enable one skilled in the art to use the invention for treating tumors generally. Specifically, the Examiner alleges that *In re Buting*, 418 F.2d 540, 543, 163 USPQ 689, 690 (CCPA 1969), stands for the proposition that evidence of one compound's use in treating two types of cancer does not enable treatment of all cancers. The Examiner also cites two references, Draetta et al. and Lane, as evidence of the lack of enablement for treatment of all cancers. According to the Examiner, Draetta et al. details the advances in the treatment of cancer and concludes that no "cure" has yet been found to encompass all cancers. Also, according to the Examiner, Lane reports that

Applicants: Breslow et al.
Serial No.: 10/054,585
Filed : November 12, 2001
Page 7

"not all" phototherapy has proven effective for all tumors.

In response, applicants respectfully traverse the Examiner's rejection.

The test for enablement under 35 U.S.C. §112, first paragraph, is whether one skilled in the art could, at the time of the invention, make and use the claimed invention based on the disclosure and the information known in the art without undue experimentation. *In re Wands*, 858 F2d. at 737, 8 USPQ2d at 1404 (CAFC 1988); *United States v. Telectronics, Inc.*, 857 F2d. at 785, 8 USPQ2d at 1223 (CAFC 1988). Applicants maintain that the claimed invention satisfies the test for enablement, and that the Examiner has not set forth sufficient grounds for concluding otherwise.

Claims 28-32 provide methods of killing tumor cells using the claimed compositions. Applicants stress that the claimed methods are directed to *killing tumor cells*, not to the treatment of cancer. These methods are based on the following facts: 1) light can be applied in a spatially selective manner to cells which are fixed in space, i.e. tumor cells; 2) the claimed compositions, when exposed to light, release photosynthesizers that generate singlet oxygen due to the absorption of the light, as described in the specification *inter alia* at page 18, line 8 to line 13; and 3) singlet oxygen can be used to kill cells.

In response to the Examiner's reliance on the decision of *In re Buting*, applicants disagree, and maintain that the Examiner has misinterpreted this case. *In re Buting* stands for the

Applicants: Breslow et al.
Serial No.: 10/054,585
Filed : November 12, 2001
Page 8

proposition that claims to the treatment of specific disease conditions warrant careful review under 35 U.S.C. §101 as credibility of an asserted utility may be harder to establish where current scientific knowledge is lacking. It does not stand for the proposition that such inventions necessarily lack utility and/or enablement. According to M.P.E.P. §2107.03(VI), the fact that there is no known cure for a disease cannot serve as the basis for rejection. Further, M.P.E.P. §2107.03(VI) states that "[a]n assertion that a claimed invention is useful in treating a symptom of an incurable disease may be considered credible by a person of ordinary skill in the art on the basis of a fairly modest amount of evidence or support." As detailed below, such support was known to one skilled in the pertinent art at the time of filing.

Applicants further maintain that it is irrelevant to the patentability of these method claims whether a treatment or a cure for particular cancers exists; it is only relevant, for purposes of enablement, whether one skilled in the art would require *undue* experimentation to practice the claimed method. The level of skill in the pertinent art is such that a physician would need no undue experimentation to practice the invention. The methods of administration, dosage and working examples which the Examiner alleges are lacking can be found in the prior art. For example, Morgan et al., Production And Use Of Porphyrin Derivatives And Of Compositions Containing Such Derivatives, U.S. Patent No. 4,988,808 (submitted in connection with the subject application as Exhibit 7 of the March 8, 2002 Information Disclosure Statement), teaches methods of administration, *inter alia* at page 14, line 63 to

Applicants: Breslow et al.
Serial No.: 10/054,585
Filed : November 12, 2001
Page 9

page 15, line 34; dosages, *inter alia* at page 15, line 35 to line 51; illumination methods, *inter alia* at page 15, line 52 to line 59; and working examples, *inter alia* at page 11, line 39 to line 69. Moreover, applicants stress that compliance with the enablement requirement does not require the disclosure of a working example. "The specification need not contain an example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without undue amount of experimentation." *In re Brokowski*, 422 F2d. at 908, 164 USPQ at 645 (CCPA 1970). Accordingly, applicants maintain that the Examiner has failed to establish a need for undue experimentation, and hence, failed to demonstrate a lack of enablement.

In view of the above remarks, applicants maintain that claims 28-32 are enabled and satisfy the requirements of 35 U.S.C. §112, first paragraph.

Conclusion

For the reasons set forth hereinabove, applicants respectfully request that the Examiner reconsider and withdraw the rejections, and solicit allowance of the pending claims.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

Applicants: Breslow et al.
Serial No.: 10/054,585
Filed : November 12, 2001
Page 10

No fee is deemed necessary in connection with this Communication. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
Commissioner for Patents,
P.O. Box 1450
Alexandria, VA 22313-1450
Mail Stop: AF

Alan J. Morrison
Reg. No. 37,399

Date

8/29/03

John P. White
Registration No. 28,678
Alan J. Morrison
Registration No. 37,399
Attorneys for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036
(212) 278-0400